



Training Proposal for:
Edwards Lifesciences LLC
Agreement Number: ET12-0211

Panel Meeting of: **December 16, 2011**

ETP Regional Office: **San Diego** Analyst: J Davey

PROJECT PROFILE

Contract Type: Priority/Retrainee Industry Sector(s): Biotechnology/Life Sciences

Counties Served: Orange Repeat Contractor: ☒ Yes ☐ No

Union(s): ☐ Yes ☒ No Priority Industry: ☒ Yes ☐ No

No. of Employees in CA: 2,467 No. of Employees Worldwide: 7,415

| Turnover Rate % | Manager/ Supervisor % |
|-----------------|--------------------------|
| 5% | 18% |

FUNDING DETAIL

| Program Costs | Substantial Contribution | Total ETP Funding | In-Kind Contribution |
|---------------|--------------------------|-------------------|----------------------|
| \$499,590 | \$149,877 | \$349,713 | \$595,665 |

TRAINING PLAN TABLE

| Job No. | Job Description (by Contract Type) | Type of Training | Estimated No. of Trainees | Range of Hours | | Average Cost per Trainee | Post-Retention Wage |
|---------|---------------------------------------|---|---------------------------|------------------|-----|--------------------------|---------------------|
| | | | | Class / Lab | CBT | | |
| 1 | Priority/Retrainee | Continuous Improvement, Management Skills, Manufacturing Skills | 427 | 24 - 200 | 0 | \$819 | \$15.37 |
| | | | | Weighted Avg: 65 | | | |

Minimum Wage by County: Orange County minimum wage of \$15.37 per hour.

Health Benefits: ☒ Yes ☐ No This is employer share of cost for healthcare premiums – medical, dental, vision.

Used to meet the Post-Retention Wage?: ☒ Yes ☐ No

Employer paid health benefits of up to \$4.27 per hour may be used to meet the Post-Retention Wage.

| Wage Range by Occupation | |
|-----------------------------|------------|
| Occupation Title | Wage Range |
| Engineers | |
| Managers/Supervisors | |
| Production Operators | |
| Professional Administrative | |

INTRODUCTION

In this proposal, Edwards Lifesciences LLC (Edwards) seeks funding for retraining as outlined below:

Founded in 1958 and headquartered in Irvine, Edwards is in the science of heart valves and hemodynamic critical care monitoring. The company focuses on medical technologies. The company's offerings include tissue replacement heart valves and valve repair products, hemodynamic monitoring devices, as well as technologies that facilitate on-pump cardiac surgery procedures through smaller incisions. Edwards develops new investigative technologies designed for the non-surgical replacement of heart valves and is also developing a blood/glucose monitoring system for the hospital environment. This is the company's fifth ETP-funded project, the third in the last five years. Edwards proposes to train 427 currently employed frontline workers and managers/supervisors at its Irvine facility.

The company qualifies for standard ETP funding as a manufacturing company in a priority industry, with out-of-state competition. (Title 22, California Code of Regulations, Section 4416(d)(2).)

Edwards' primary business at its Irvine location is researching, developing and manufacturing bioprosthetic tissue heart valves and critical care technologies. These businesses continue to grow and require incumbent workers to receive cross-functional skills in these and newer products.

Edwards reports that with the successful launch and commercialization of the Transcatheter heart valve in Europe, and with the recent approval and launch of the product in the United States, it is expecting increased demand for this technology. This new product will likely be produced in Irvine. Despite the recent global economic recession, Edwards is hiring new employees in 2012 to keep pace with increased growth. (Edwards was approved by the Panel in May 2011 for a Job Creation training project for 85 newly-hired temp-to-permanent trainees.)

In order to keep pace with increased demand and new product development, Edwards must train its incumbent workers the skills needed to keep pace with a growing enterprise.

PROJECT DETAILS

In its first prior two projects, Edwards initiated formal training to implement Continuous Improvement using intermediate problem solving, Lean quality tools, and other techniques. Edwards also made changes to its manufacturing process and completed production-related training. For example training included in previous Agreements introduced Catalyst, a corporate product development initiative that defined team member roles and other basic quality processes.

Edwards' third prior project continued to build on employee skills in more advanced medical devices. For example, Edwards developed the Transcatheter aortic heart valve as discussed above. The fourth project is active, currently training 85 newly-hired retrainees to meet expansion of its new and existing products.

Under this proposal, Edwards will provide training to 427 Engineers, Managers/Supervisors, Production Operators and Professional Administrative Staff in advanced skills for the heart valve division and other emerging technologies.

In the past, each heart valve was constructed entirely by one "biological" Production Operator. Now, the manufacturing process valve has been broken down into smaller steps, streamlined and upgraded to make it more efficient. As a result, each Production Operator achieves competency on a step sooner, reducing training-to-production time drastically. Production team members are certified in at least 6 of these steps. To attain FDA-level competency, each Production Operator had to learn every step in producing a complete valve before they were allowed to work on saleable ones. This new process also allows the employee to achieve higher quality, as each Production Operator checks the work of the previous operation before doing his/her part of the operation. Production Operators are then cross-trained in the other portions of the manufacturing line.

In addition to upgrading/streamlining manufacturing processes for individual valves, Production Operators will also be cross-trained on different product lines. For example, surgical heart valves and Transcatheter heart valves are different products. In the past, Production Operators were assigned to work on one or the other, but not both. Now, Production Operators may train on both product lines, with the aim of increasing the flexibility of the manufacturing organization. There are no temp-to-perm trainees included in this proposal.

Trainees will receive training in the following skills:

Continuous Improvement – Engineers, Managers/Supervisors and selected Professional Administrative Staff will receive a curriculum that focuses on project management skills. Because the development of Edward's products often involve large scale projects, with complex requirements and tight deadlines, project management skills are essential. Although many individuals have had some project management training, this training will be more in-depth. Classes such as Lean manufacturing, process improvement, problem-solving and teambuilding will also be provided as they relate to project management.

Management Skills – This training will be offered to Managers and Supervisors in leading change, strategy, and leadership. With the growth that Edwards has experienced in the past few years, leadership skills are more critical to the success of the business than ever.

Manufacturing Skills – Production Operators will learn training is necessary for production workers that don't have the skills necessary to sew heart valves to the strict specifications. This position takes months of practice to ensure a very high quality product.

Commitment to Training

Edwards continues to make investment in technical and laboratory training to support the development of new products, improve business processes and its quality systems. Edwards training budget was \$2,000,000 for 2011.

Edwards will continue to fund all training in OSHA-mandated safety regulations, sexual harassment prevention, and new hire orientation. In addition Edwards continues to train organization wide in a wide variety of training curriculum based on job occupation.

The types of training Edwards has provided in the past with its budgeted training dollars:

| | |
|----------------------------------|---|
| Manufacturing Production Workers | Safety, Emergency Preparedness, Good Documentation Practices, Production skills |
| Managers/Supervisors | Sexual Harassment Prevention, Disability, Quality System Fundamentals, Affirmative Action, Global Business Practices, Best Management Practices, Finance for Non-Financial Managers |
| Engineers, Scientists | Quality System Fundamentals, Global Business Practices, Employee Health and Safety; Project Management, Six Sigma |
| Professional Administrative | Quality System Fundamentals, Global Business Practices, Employee Health and Safety, Six Sigma Green Belt |

Prior Performance

In its previous three ETP training projects, Edwards has performed at an average 72%, training and retaining 1,320 trainees, most of them newly hired employees. See discussion of ET07-0357 in prior projects table.

Substantial Contribution

Edwards is a repeat contractor with payment earned in excess of \$250,000 and a former Substantial Contribution at the 15% level, at the Irvine facility, within the past five years. (See Prior Project Table.) Accordingly, reimbursement for trainees at this facility will be reduced by 30% to reflect the company's \$149,877 Substantial Contribution to the cost of training.

RECOMMENDATION

For the reasons set forth above, staff recommends approval of this proposal.

ACTIVE PROJECTS

The following table summarizes performance by Edwards under an active ETP Agreement:

| Agreement No. | Approved Amount | Term | No. Trainees (Estimated) | No. Completed Training | No. Retained |
|---------------|-----------------|------------------|--------------------------|------------------------|--------------|
| ET11-0267 | \$299,880 | 6/1/11 – 5/31/13 | 85 | 0 | 0 |

ET11-0267 – Representatives from the company state that training under this Job Creation Agreement (approved in April 2011) is performing as planned, with over 100 trainees enrolled.

PRIOR PROJECTS

The following table summarizes performance by Edwards under ETP Agreements that were completed within the last five years:

| Agreement No. | Location (City) | Term | Approved Amount | Payment Earned |
|---------------|-----------------|-------------------|-----------------|----------------|
| ET09-0503 | Irvine | 5/4/09 – 5/3/11 | \$489,048 | \$489,048 |
| ET07-0357 | Irvine | 5/8/07 – 5/7/09 | \$1,738,800 | \$660,777 |
| ET05-0312 | Irvine | 5/30/05 – 5/29/07 | \$1,224,500 | \$840,833 |

ET09-0503 – Agreement closed early at 100% performance.

ET07-0357 – Edwards' representatives state that training under this Agreement was directly affected by the company's business performance in 2007. During this period, the company faced financial pressure due to a decline in sales as a result of competitor gains into Edwards' core heart valve business and the lack of new product launches into the marketplace. Edwards focused on measures throughout 2007 to control costs including, cutting non-critical expenditures related to travel and training. As a result, ETP training planned for 2007 was not delivered.

ET05-0312 – Edwards' trained and retained 385 (77%) trainees. Over 89% of ETP payment was earned in this Agreement.

DEVELOPMENT SERVICES

Edwards retained California Manufacturing & Technology Association (CMTA) in Sacramento to assist with development of this proposal for a flat fee of \$10,000.

ADMINISTRATIVE SERVICES

CMTA will also perform administrative services in connection with this proposal for a fee of \$29,988, not to exceed 10% of payment earned.

TRAINING VENDORS

To Be Determined

Exhibit B: Menu Curriculum**Class/Lab
Hours**

24 – 200

Trainees will receive any of the following:

CONTINUOUS IMPROVEMENT SKILLS

- Lean Manufacturing
- Problem-Solving/Troubleshooting Skills
- Production Operations
- Process Improvements
- Teambuilding
- Quality Concepts
- Project Management

MANUFACTURING SKILLS

- Production and Equipment Operations
- Manufacturing Biological and Non-biological Products
- Cross-Functional Skills for Frontline Workers
- Manufacturing Assembly Standards and Procedures

MANAGEMENT SKILLS (Managers & Supervisors only)

- Change Management
- Leadership Skills
- Business Acumen
- Leading Across Organizational Boundaries

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|---|
| Reimbursement for retraining is capped at 200 total training hours per trainee, regardless of the method of delivery. |
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